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EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
01/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/782,266	BESSELINK, PETRUS A.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-95,113-122,127-141 and 143-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-95,113-122,127-141 and 143-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 127 and 129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 127 and 129 recite the limitations "the first arcuate member" and “the second arcuate member”. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 91-95, 134, and 143** are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (US 5,895,406). Gray discloses a method of applying a radial force against a

surface of a passageway with an expandable device comprising providing an expandable device with a plurality of cells, at least one cell capable of being expanded between a stable contracted state and a stable expanded state and radially expanding the expandable device against a surface of the passageway (col. 3 ll. 28-33), wherein each cell comprises a generally longitudinal wave-like first member and a generally longitudinal wave-like second member, the first and second members being generally in phase when the cell is in an unexpanded state and generally out of phase when the cell is in an expanded state (figs. 3a, 3b).

6. Regarding claim 92, see col. 3 ll. 26-27.

7. Regarding claim 93, see fig. 4. The stent can be considered a liner as it lines a blood vessel.

8. Regarding claim 95, Gray discloses that the ends of the stent may have an increased thickness (col. 3 ll. 58-60). The struts at the ends of the stent will be thicker than struts towards the middle of the stent.

9. Regarding claim 134, Gray discloses placing the stent within a body of a patient (col. 5 ll. 20-24).

10. Regarding claim 143, Gray discloses that the stent may be made from shape-memory material (col. 5 ll. 9-10 and 16-19) and therefore can be considered capable of assuming a stable collapsed configuration and a stable expanded configuration without any stable configurations therebetween. For example, cold saline solution could be delivered to keep the stent in its collapsed form while in the catheter. Once delivered, the stent is stable in its expanded form at body temperature.

11. **Claims 113, 118, 135, 139, and 141** are rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter et al. (US 5,643,314; “Carpenter”). Regarding claims 113, 122, and 130, Carpenter discloses a method of stabilizing an unsupported section of a passageway

comprising providing an expandable device having one or more cells, each of the cells comprising first and second arcuate members (for example, two adjacent rings), placing the device at a passage in the passageway while in a first stable state, and expanding the one or more cells to a transition point defining a geometry of one or more cells at which no additional force is necessary to further expand the one or more cells, permitting the one or more cells to continue to expand beyond the transition point without the application of additional force (see entire document, esp. col. 4 ll. 64-col. 5 ll. 20). In particular, Carpenter et al. discloses partially inflating a balloon to apply an expansive force to the inner surface of the stent to overcome the locking action provided on the stent so that the stent is free to self-expand. The transition point geometry is considered the cells' geometry at the point where the lock is freed. At least a portion of the first arcuate member (one of the rings) is generally concave before the one or more cells has been expanded and at least a portion of the first arcuate member is generally convex after the one or more cells has been expanded beyond the transition point. It is noted that the portions (first "at least one portion" and second "at least one portion) do not need to be the same portion of the first arcuate member. Therefore, if the left half of one of the rings of Carpenter is considered convex, the right half is concave. When considering the left half as the first "at least a portion", this portion is convex before the cell has been expanded (and after). When considering the right half as the second "at least a portion", this portion is concave after the cell as been expanded (as well as before).

12. Regarding claim 118, Carpenter teaches expanding the device to a first and second stable size.

13. Regarding claim 135, the device of Carpenter is a generally tubular stent delivered into a body of a patient.

14. Regarding claim 141, the entire device of Carpenter can be considered a single unit since the cell must comprise first and second arcuate members and may include other elements.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **Claims 119-122, 127-129, 136, 137, and 144** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray. Gray discloses a method comprising an expandable device with a plurality of bistable cells, each of the bistable cells comprising first and second arcuate members, each cell capable of assuming a stable collapsed configuration in which the first and second arcuate members are in phase and a stable expanded configuration in which the arcuate members are out of phase, the expandable device having a generally tubular shape. As discussed above, the device may be shape memory and can be stable in the collapsed configuration at a first cooler temperature and stable in the expanded configuration at body temperature. No stable configurations will exist between these two configurations using the two temperatures. Alternatively, it is noted that bistable can include more than 2 stable positions as indicated in the instant application (page 19, ll. 22-23). When the device of Gray is balloon expandable, it will be stable in both the collapsed and expanded configuration. Gray does not expressly disclose surrounding the expandable device with an expandable liner element attached to an outer surface of the device. However, expandable, deformable, and elastomeric material grafts, sleeves, or coating applied to stents are well known in the art and the step of attaching such a material to the stent of Gray would have been obvious to one skilled in the art

as it is sometimes desirable to completely isolate a portion of the body passageway from blood passing through it or increase the biocompatibility of a stent through a graft covering.

17. Regarding claim 129, Gray discloses that the ends of the stent may be thickened. If a first arcuate member in the middle of the stent is considered, it will have a greater flexibility than a thicker second arcuate member at the end of the stent (see also 35 USC 112 2nd par. rejections above).

18. Regarding claim 144, as discussed above, the device may be shape memory and can be stable in the collapsed configuration at a first cooler temperature and stable in the expanded configuration at body temperature (col. 5 ll. 9-10 and 16-19). No stable configurations will exist between these two configurations using the two temperatures.

19. **Claim 140** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Wiktor (US 4,886,062). Gray discloses the invention substantially as stated above but does not expressly disclose locating multiple stents in the passageway such the ends of adjacent stents overlap forming a continuation of the liner element against he inner diameter of the passageway. However, Wiktor teaches that it is well known to employ multiple stents in tandem and further discloses that a balloon and stent assembly can be fed through a previously implanted stent so that a second stent may be implanted downstream of the first stent (col. 5 ll. 3-9). It would have been obvious to one skilled in the art to have modified the method of Gray to include implanting several stents within the passageway as taught by Wiktor in order to treat a larger area of a vessel. Regarding the overlapping ends, such a modification would have been obvious in order to ensure that no portion of the vessel is untreated between the stents.

20. **Claims 114-117** are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter. Carpenter discloses the invention substantially as stated above but fails to disclose attaching a wrapping or liner to the outer surface of the device or isolating a portion of the

passageway with the expandable device. However, expandable, deformable, and elastomeric material grafts, sleeves, or coating applied to stents are well known in the art and the step of attaching such a material to the stent of Carpenter would have been obvious to one skilled in the art as it is sometimes desirable to completely isolate a portion of the body passageway from blood passing through it or increase the biocompatibility of a stent through a graft covering.

21. **Claims 130-133, 138, 145, 146, 148, and 149** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Lock et al. (US 5,383,926; "Lock"). Gray discloses a method of expanding an expandable device in a passage way comprising providing an expandable device having at least one cell, the at least one cell comprising first and second members, at least a portion of the second members being more pliable than the first members. For example, when considering a portion of a second member that is remote from a connecting piece (8) and comparing it to a portion of a first member that is immediately adjacent a connecting piece, the second member portion is more pliable than the first member portion. Gray discloses positioning the expandable device in a blood vessel. Gray discloses at least a portion of the at least one cell moving between a generally concave state and a generally convex state at a transition point (see figs. 3a, 3b). Gray discloses that the device may be either self-expandable or balloon expandable but does not disclose first applying a radially outward force to expand the cell to a transition point and permitting the cell to continue to expand without the application of additional force.

22. Lock teaches that it is well known to include connecting strips on a stent that initially limit expansion of a stent. A balloon is used to initially expand the stent. Once a certain amount of expansion has taken place, the strips are broken by further radial force applied to the stent (col. 3 ll. 47-51, col. 4 ll. 45-66, col. 5 ll. 18-34). At this point, the stent may self-expand to conform to the expanded configuration. This is advantageous because the stent can be enlarged when the

body vessel experiences circumferential growth or a later secondary dilation of the stent is necessary. It would have been obvious to incorporate some sort of limiting means on the device of Gray, such as strips which temporarily restrain the stent after an initial expansion, so that it too would have these advantages.

23. Regarding claims 146 and 149, the second members can include the connecting members (8) which are rigid and interconnected by the arcuate sections of the second members.

24. Regarding claim 148, the second member comprises three generally linear portions cumulatively forming either a generally concave or convex shape. For example, looking at one of the end crests of the second member shown in fig. 3a, each side of the crest can be considered generally straight and the portion connecting them can be considered generally straight (note "generally" straight).

25. **Claim 147** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray in view of Lock as applied to claim 130 above and further in view of Sgro (US 5,496,365). Gray in view of Lock discloses the invention substantially as stated above except for hinges. Sgro teaches that it is well known to include thinner sections of stent struts which serve as hinges (21) to facilitate relative movement of sections of the struts (fig. 11; col. 4, ll. 16-20). It would have been obvious to include such hinges on the second member in areas where the member alternately straightens out and curves in order to facilitate expansion and collapsing of the filter.

Response to Arguments

26. Applicant's arguments with respect to independent claims 91, 119, 122, and 130 and the claims which depend therefrom have been considered but are moot in view of the new ground(s) of rejection.

27. Applicant's arguments regarding the amendment to claim 113 overcoming the US 102(e) rejection of claim 113 over Carpenter are not found persuasive. It is noted that the "at least a portion of the first arcuate member" which appears in line 12 of the claim is not the same as the "at least a portion of the first arcuate member" which appears in line 13 of the claim. If the left half of one of the rings (first arcuate member) of Carpenter is considered convex, the right half is concave. When considering the left half as the first "at least a portion", this portion is convex before the cell has been expanded (and after). When considering the right half as the second "at least a portion", this portion is concave after the cell as been expanded (as well as before) since its concavity is opposite that of the left half.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 1/15/2009

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731